Please amend claims 7-9 to read as follows. A marked-up copy of the previous claim showing all the changes made thereto and appended to this Response.

7. (Twice Amended) An isolated polypeptide having the ability to bind lactose and consisting of at least 30 contiguous amino acids from the sequence of SEQ ID NO:2.

8. (Twice Amended) An isolated, naturally occurring allelic variant of a SEQ ID NO:2, wherein the variant is encoded by a nucleic acid molecule which hybridizes in 1X SSC at 65°C, followed by one or more washes in 0.3X SCC, at 65°C to a complement of a nucleic acid having a nucleic sequence of SEQ ID NO:3.

9. (Twice Amended) An isolated polypeptide which is at least 90% identical to a polypeptide comprising the amino acid sequence of SEQ ID NO:1 or 2.

REMARKS

Claims 7-9 have amended to better recite the patentable nature of the present invention. No new matter has been added.

Claims 7, 8, 10, 16 and 17 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter of the present invention. In response, claims 7 and 8 have been amended in conformity with the Examiner's kind suggestion. Additionally, claims 7 and 8 have been

amended to provide proper U.S. format for dependent claims 16 and 17. Accordingly, this rejection is overcome.[1/]

Claims 7-10, 16 and 17 stand rejected under 35 U.S.C. §112, first paragraph, as being drawn to subject matter which was not described in the specification in such a way as to reasonably convey to those skilled in this art that Applicants had possession of the claimed invention when this case was filed. In response, Applicants wish to point out that the subject matter of claim 7 is set forth at specification page 10, line 2, the subject matter of claim 8 is set forth at specification page 10, line 16, and the subject matter of claim 9 is set forth at specification page 9, line 23. Accordingly, this rejection is thought to be overcome.[2/]

Claims 6, 7 and 9 stand rejected under 35 U.S.C. §102(a) as anticipated by Accession No. LEG9_HUMAN. In response, Applicants are currently obtaining both a certified copy and verified translation of their priority document. Such will be filed as soon as possible, and so, this rejection overcome.

Claims 7 and 9 stand rejected under 35 U.S.C. §102(a) as anticipated by *J. Biol. Chem.*, Vol. 273, (1998) 16976-84 (Matsumoto). This rejection will be overcome by the priority documents.

Claims 7 and 10 stand rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,027,916 to Ni. Claims 7 and 10 also stand rejected under 35 U.S.C.

[1/] As to claim 10, it is thought to have been rejected in this paragraph solely as being dependent from rejected claim 7. If this is incorrect, then clarification is requested.

[2/] In this regard, it is not well-understood why claim 7 need recite any function; it is thought to be understood such oligomers can be well-utilized as antigens (page 1, line 26). Nonetheless, simply in order to reduce the issues, that claim has been amended to recite having an ability to bind lactose, as the Examiner suggested.

§102(b) as anticipated by *J. Biol. Chem.*, Vol. 272 (1997) 6416-22 (Tureci). In response, claim 7 is amended to recite that the isolated polypeptide consists of at least 30 amino acids from SEQ ID NO:2. Whatever else Ni and Tureci teach, they do not disclose anything that consists of a portion from SEQ ID NO:2 that is at least 30 amino acids long.[3/]

Claims 6-10 and 15-17 remain rejected under 35 U.S.C. §101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Previously, Applicants pointed out that the claimed subject matter is a full-length clone that encodes a protein isolated from human stomach cancer cell line that is sufficiently similar to human G9 that those of ordinary skill expect it to share activity with these this galectin.

At the very least, the resemblance of the present invention to such specific protein makes it clear the present invention can be further utilized as research tools for better characterizing that prior art compound.[4/]

In response, the Examiner states (1) Applicants' asserted utility (binding sugars) is not specific, e.g., it is applicable to "numerous carbohydrate binding proteins", and (2) Applicants' statement (in the specification) based on sequence similarity, galectin-9 would have inherent utility as a member of the galectin family is insufficient. Those points are addressed in turn.

[3/] Claim 10 has been cancelled as being inconsistent with claim 7 as amended.

[4/] The complete role of galectin-9 is not yet determined. Page 2, lines 3-6.

At the outset, it is not seen at all why sugar-binding is some trivial or non-specific utility.[5/] As the Examiner acknowledges, not all proteins bind sugars. Moreover, even a brief search of the PTO database research 16 patents issued since 1982 with the phrase "sugar binding" in their claims. (See, e.g., claim 1 of U.S. Patent No. 5,908,761 entitled Galectin-8 and Galectin-8-like proteins and DNA molecules coding therefor.[6/]) Obviously, for this reason alone, such is therefor a plainly important consideration and feature generally, and therefore that binding ability certainly satisfies the threshold test of 35 U.S.C. §101 per se. Nonetheless, if such will be helpful to resolution of this case, Applicants will be happy to submit a Declaration under Rule 132 establishing that such activity is substantial to those of ordinary skill.

The Examiner also objects to any basis of utility due to the disparate nature of the galectin "family." However, Applicants did not allege utility based on similarity to galectin-1 (page 2 of the Office Action, line 28) or galectin-3 (page 3, line 1). Rather, the specification clearly establishes high similarity to galectin-9 which, at the very least, is understood to be an antigenic protein indicated in Hodgkins disease and is considered as well to be involved in cell adhesion. These activities are both substantial and specific. Moreover, their credibility is not in dispute.

To the extent the claims are rejected under 35 U.S.C. § 101 as not having a specific and substantial utility that is credible (USPTO Utility Examination Guidelines, 66 Fed. Reg. at 1098), the Office Action necessarily contends (although unstated) the activity

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5/ The complaint that numerous carbohydrate binding proteins are known is, at best, a tautology.

6/ See also, claims 75, 76 and 78 of U.S. Patent No. 5,834,247.

of the present invention is not credible. Implicitly at least, the Office Action must argue the pending claims do not satisfy the utility requirement of 35 USC 101 because, given the state of the art, structure-function analysis is unpredictable. This basis of rejection is, respectfully submitted, without foundation either in law or in fact.

Any reliance on the unpredictability of protein activity from known homologous sequences is not well-taken by those of ordinary skill. See, e.g., Principles of Protein Structure, Cantor, ed. (1978) 167 wherein it is explicitly taught that

> "[h]omologous proteins result from speciation or differentiation. Comparisons between homologous proteins have yielded general rules for protein structures (citing Schulz, Angew. Chem. Int. Edit., Vol. 16 (1977) 23-33). . . . In this context it is often useful to distinguish between protein speciation and protein differentiation (citing Molecular evolution and Polymorphism, Kimura ed. (1977) National Institute of Genetics, Mishima, Japan). Speciation is the evolution of homologous proteins possessing a common function in different organisms."

This knowledge is summarized in the art as evidencing that establishing homology between the unknown and reference proteins permits the skilled artisan to assume the unknown unexpressed protein and the known reference protein have the same function. Functional Genomics, Science, Vol. 278, No. 601 (1997).

This is not an aberrant position; similarly, the American Society of Human Genetics ("ASHG") similarly acknowledges "sequence homology is a useful predictor of gene function." Letter from Ronald Worton, Ph.D., President, ASHG, to the Honorable Q. Todd Dickinson, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, Unites States Patent and Trademark Office at 2 (Mar. 22, 2000) (on file with the USPTO).

Additionally, the USPTO recognizes the state of this art in Example 10 of the Utility Training Materials: DNA fragments encoding a Full Open Reading Frame (ORF). In the example the Examiner is directed not to reject the claims merely because the applicant's asserted utility is premised on the "overall level of sequence similarity between [the unknown sequence] and the consensus sequence of the known DNA ligases that are presented in the specification." Indeed, Example 10 acknowledges that "homology between the known and unknown protein is sufficient to ascribe the known protein's function to the unknown; thus the claim possesses credible, substantial, and specific utility." Id. at 54.

Moreover, the PTO acknowledges as well utility is well-established if it is readily apparent to one skilled in the art. Id. at 55. This is in conformity with the law promulgated by the Federal Circuit, which notes 35 U.S.C. 112 can be satisfied even by "genus claims to nucleic acids based on their hybridization properties, . . . [if the subject matter of the claims will] hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally similar." Enzo Biochem v. Gen-Probe, Appeal No. 01-1230 slip op. granting reh'g at 15 (Fed. Cir. July 15, 2002).

See for instance, in In re Folkers, 145 USPQ 390 (CCPA 1965), where a new compound belonging to the known family of quinones and hydroquinones was alleged, without more, to have the electron transport activity of that known class. Id at 393. The predecessor court to the Federal Circuit held that function is inferred based on similarity to a substance with a known function. Id. Similarly, in In re Brana 34 USPQ 1436, 1442 (Fed. Cir. 1995) the Federal Circuit noted

> "[a]lthough it is true that minor changes in chemical compounds can radically alter their effects on the human body, evidence of success in structurally similar compounds is relevant in determining whether one skilled in the art would believe an asserted utility."

Regarding the asserted utility to better characterize prior art galectin-9, such utility too is specific, when the gene being probed for is already known. Revised Interim Utility Guidelines Training Materials at 50-53.

In this regard, the PTO decided long ago that the ESTs must be rejected since use as research tools is not specific and they have insufficient homology to support a specific, substantial and credible utility. However, such logic (used in the context of ESTs) does not extend to full-length homology-based sequences if the homologous prior art sequence has a known function, since their use as research tools is plainly specific to the homologous prior art sequence. See the Federal Circuit Bar Journal, Vol. 11, No. 4 (2002) 918.

Accordingly, respectfully submitted, the rejection under 35 U.S.C. § 101 is overcome and withdrawal thereof is earnestly solicited.

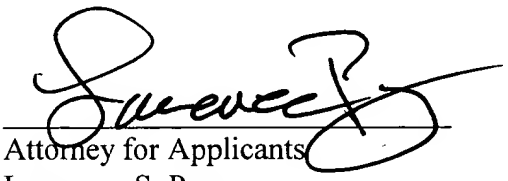
Claims 6-10 and 15-17 are also rejected under 35 U.S.C. §112 first paragraph. In support of this rejection, the Examiner states that because the invention is not supported by a substantial asserted utility, one of ordinary skill would not know how to use it. However, as seen explained above, the present invention is supported by a specific and substantial utility. Moreover, as seen from a cursory review of the art (see, e.g., U.S. Patent No. 5,908,761 teaching use of galectin-8 molecules, discussed previously), those of ordinary skill plainly know how to utilize the subject matter of the pending claims.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 6-9 and 15-17 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE TO CLAIMS

7. (Twice Amended) An isolated [polypeptide consisting of a fragment of a] polypeptide having the ability to bind lactose and consisting of at least 30 contiguous [comprising the] amino acids from the sequence of SEQ ID NO:2[, wherein the fragment comprises at least 30 contiguous amino acids of SEQ ID NO:2].

8. (Twice Amended) An isolated, naturally occurring allelic variant of a [polypeptide comprising the amino acid sequence of] SEQ ID NO:2, wherein the [polypeptide] variant is encoded by a nucleic acid molecule which hybridizes in 1X SSC at 65°C, followed by one or more washes in 0.3X SCC, at 65°C to a complement of a nucleic acid having a nucleic sequence of SEQ ID NO:3.

9. (Twice Amended) An isolated polypeptide which is at least 90% identical to a polypeptide comprising the amino acid sequence of SEQ ID NO:1 or 2.

10. Cancelled.